UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MDL NO. 13-02419-RWZ

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

MEMORANDUM OF DECISION

January 13, 2015

ZOBEL, D.J.

On May 7, 2014, defendants Advanced Pain & Anesthesia Consultants, P.C. d/b/a APAC Centers for Pain Management ("APAC") and Randolph Y. Chang, M.D. ("Chang"), sought dismissal of all claims against them in two actions direct-filed in this court through MDL short-form complaints[1] for lack of personal jurisdiction, or in the alternative, failure to state a claim under Fed. R. Civ. 12(b)(1) & (6) (Docket # 1108).

After that filing, plaintiffs brought identical suits in the Northern District of Illinois which were subsequently transferred to this MDL (hereinafter "the Illinois-filed actions"). See Musselwhite v. Advanced Pain & Anaesthesia Consultants, P.C., d/b/a Apac Centers For Pain Management et al, No. 1:14-cv-13676-RWZ (filed 9/23/2014), Kennedy et al v. Advanced Pain & Anesthesia Consultants, P.C. et al, No. 1:14-cv-13689 (filed 9/24/2014).

APAC and Chang sought dismissal of all claims against them in the direct-filed

[1] Musselwhite, et al. v. Advanced Pain & Anesthesia Consultants, P.C., et al., No. 1:13-cv-13228-RWZ, and Kennedy v. Advanced Pain & Anesthesia Consultants, P.C., et al., No. 1:13-cv-13227-RWZ (hereinafter "the direct-filed cases").

actions for lack of personal jurisdiction, and in the direct-filed and Illinois-filed actions, for failure to state a claim under Fed. R. Civ. P. 12(b)(1) & (6) (Docket # 1208). The parties later agreed by stipulation to consolidate the direct-filed actions into the Illinois-filed actions[2] and adopt APAC and Chang's motion to dismiss in the consolidated action. See Docket # 1605. Defendants also withdrew without prejudice their jurisdictional arguments under Rule 12(b)(1)[3], and plaintiffs withdrew their claims for conspiracy, agency, and battery in the consolidated action. For the reasons that follow, defendants' motion is DENIED IN PART and ALLOWED IN PART.

I. Background[4]

A. The Multidistrict Litigation

This multidistrict litigation stems from an outbreak of fungal meningitis caused by contaminated methylprednisolone acetate ("MPA") manufactured and sold by the New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"). NECC operated a compounding pharmacy in Framingham, Massachusetts, that combined and mixed ingredients to create specific formulations of pharmaceutical products. In the Fall of 2012, health officials traced a number of cases of fungal meningitis to injections of MPA that had been manufactured by NECC. NECC initiated

[2] Such consolidation is now ORDERED.

[3] It is not clear that a jurisdictional argument of this nature can be withdrawn by the parties as they raise serious questions regarding my authority to adjudicate. The consolidation of the direct-filed cases into the Illinois-filed cases, however, largely moots the jurisdictional problems presented.

[4] A detailed account of the background of the case is set forth in previous opinions of the court. See, e.g., In re New Eng. Compounding Pharm., Inc. Prods. Liability Litig., 496 B.R. 256, 260-263 (D. Mass. 2013). Only a brief summary is outlined here.

a recall of several contaminated batches of MPA before eventually surrendering its pharmacy license and ceasing production of all pharmaceutical products. NECC filed for Chapter 11 bankruptcy in December 2012.

Lawsuits alleging death or injury caused by contaminated MPA were filed against NECC, affiliated entities and individuals, and/or health care providers in multiple state and federal jurisdictions around the country beginning in November 2012. In February 2013, the Judicial Panel on Multidistrict Litigation ("JPML") issued an order under 28 U.S.C. § 1407 transferring a number of cases pending in several federal courts to this court for coordinated and consolidated pretrial proceedings; subsequent JPML orders also transferred "tag-along" cases here. Other cases pending in both federal and state court were likewise transferred to this court via additional transfer orders. See In re New Eng. Compounding Pharm., Inc. Prods. Liability Litig., 496 B.R. 256 (D. Mass. 2013) (Docket # 176); In re New Eng. Compounding Pharm., Inc. Prods. Liability Litig., Civil Action No. 13-2419-RWZ, 2014 WL 2040139 (D. Mass. May 15, 2014) (Docket # 1131); June 4, 2014, Transfer Order (Docket # 1173).

On November 5, 2013, in accordance with MDL Order No. 6 (Docket # 209), the court-appointed plaintiffs' steering committee filed a master complaint against numerous non-NECC parties, including hospitals, clinics, and health care facilities (as well as their physicians, staff, agents, and employees) that allegedly obtained

contaminated MPA from NECC and administered it to their patients.[5] See Master Complaint ("Master Compl."), Docket # 545. Plaintiffs who already had cases on file or who wished to file in the multidistrict litigation thereafter filed short-form complaints to assert facts and claims as set out in the master complaint.

B. The *Musselwhite & Kennedy Actions*

The actions for decision here are Musselwhite v. Advanced Pain & Anesthesia Consultants, P.C., d/b/a APAC Centers for Pain Management et al., No. 1:13-cv-13228-RWZ, and Kennedy et al. v. Advanced Pain & Anesthesia Consultants, P.C. et. al., No. 1:13-cv-13227-RWZ (collectively the "Directly Filed actions) and Musselwhite v. Advanced Pain & Anesthesia Consultants, P.C., d/b/a APAC Centers for Pain Management et al., No. 1:14-cv-13676-RWZ (filed 9/23/2014); Kennedy et al. v. Advanced Pain & Anesthesia Consultants, P.C. et al., No. 1:14-cv-13689 (filed 9/24/2014) (collectively the "Illinois-Filed actions").

Plaintiffs allege that they were administered contaminated NECC MPA by Dr. Chang, an employee of APAC, and that they suffered injuries and damages as a result. They allege Dr. Chang and APAC owed them a duty of care based on their physician-patient relationship, and that Dr. Chang and APAC breached that duty by bulk ordering MPA from NECC through the use of lists of false patient names and failure to make any inquiry into the safety of NECC's products.

II. Legal Standard

[5] The master complaint was intended to be an administrative tool, allowing the allegations and claims against all defendants to be stated in one document.

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). Plausibility "is not akin to a probability requirement, but [requires] more than a sheer possibility that a defendant has acted unlawfully." Iqbal, 556 U.S. at 678. Thus, "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" Id. When ruling on a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the court accepts as true all factual allegations contained in the complaint, but not legal conclusions. Id.

III. Discussion

A. Motion to Dismiss for Failure to State a Claim (Docket # 1108)

Plaintiffs allege claims[6] against the defendants for common law negligence and gross negligence, violation of the Illinois consumer protection statute (Ill. Comp. Stat. Ann. ch. 815, 505/1 et seq.), common law failure to warn, Illinois product liability statutory claims, and punitive damages. Defendants assert that all these claims should be dismissed for failure to state a claim upon which relief can be granted.

1. Negligence[7] (Count III)

To prove medical negligence under Illinois law, a plaintiff must establish "a duty

[6] I address the claims as plead and litigated noting, however, that some of the "claims" are not, properly speaking, independent causes of action.

[7] To the extent plaintiffs assert a seperate claim for gross negligence as its own cause of action, it is dismissed. See Merit Ins. Co. v. Colao, 603 F.2d 654, 659 (7th Cir. 1979) ("Illinois does not recognize gross negligence as an independent ground for recovery.")

owed by defendant to the plaintiff, a breach of duty, an injury proximately caused by the breach, and resultant damages." Reynolds v. Decatur Mem'l Hosp., 277 Ill. App. 3d 80, 85, 660 N.E.2d 235, 238 (1996).

Defendants argue that plaintiffs have failed to allege any of the elements necessary for negligence or gross negligence because "Illinois law does not impose a duty on physicians to regulate pharmacies and/or engage in any type of due diligence prior to lawfully purchasing medications from a licensed pharmacy such as NECC." This position misconstrues plaintiffs' allegations. The relevant misconduct is set out in detail in the master complaint which alleges that defendants had a duty to:

- exercise reasonable care to ensure that the drugs they purchased to administer to their patients were procured from drug companies that complied with pharmaceutical laws, made safe and effective drugs, and utilized proper quality control, safety, and sterility measures;
- exercise reasonable care to avoid administering to plaintiff contaminated drugs, or drugs they knew or should have known to be contaminated;
- provide plaintiff with reasonable care and treatment;
- obtain from the plaintiff informed consent for the procedure performed, by adequately and accurately describing the nature and risks of the procedure, including the drugs that were to be administered; and
- inform plaintiff of the source of the drug (an unaccredited, mass producing, out-of state, compounding pharmacy, unregulated by the FDA) and the dangers associated therewith.

See Master Compl. at ¶¶ 226-232. The master complaint further alleges that defendants breached these duties by, among other things, failing to exercise reasonable and prudent care to ensure that the drugs they purchased and provided to plaintiffs were made and sold in compliance with all applicable pharmaceutical laws;

failing to follow certain policies and procedures to ensure such drugs were safe; failing to adequately supervise and train employees and agents who ordered the drugs; failing to promptly notify plaintiffs that they were injected with potentially contaminated steroids; and generally failing to exercise reasonable care or conduct due diligence to ensure they were not injecting contaminated and dangerous drugs into their patients. See id. at ¶ 234. Plaintiffs maintain, via the master complaint, that these breaches proximately caused their injuries and that defendants' actions "went beyond mere thoughtlessness, inadvertence or error of judgment," "constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients." Id. at ¶¶ 236-239.

Such allegations of duty are sufficient to make out claims for negligence and gross negligence under Illinois law. Defendants' motion is therefore denied as to these claims.

2. Violation of Illinois' Consumer Fraud and Deceptive Business Practices Act (Count IV)

To state a claim under the Illinois Consumer Fraud Act, a plaintiff must allege: (1) a deceptive act or unfair practice occurred; (2) the defendant intended for plaintiff to rely on the deception; (3) the deception occurred in the course of conduct involving trade or commerce; (4) the plaintiff sustained actual damages; and (5) such damages were proximately caused by the defendant's deception. Walton v. Bayer Corp. (In Re Yasmin and Yaz (Drospiernone) Marketing, Sales Practices and Products Liability Litigation), 692 F. Supp.2d 1012, 1023 (S.D. Ill. 2010).

Plaintiffs allege that defendants "deceptively concealed" information about the product actually used (NECC's MPA) by representing, among other things, that the patients "were receiving FDA-approved Depo-medrol when in fact [defendants] injected [plaintiffs] with NECC's compounded MPA." Master Compl. ¶¶ 243, 247, 251, 253. Such allegations are supported, if not proven, by subsequent invoices for Depo-medrol rather than MPA. Plaintiffs have plausibly alleged that defendants were aware of the difference in risk between NECC's MPA and its FDA-approved counterpart Depo-medrol, and concealed which drug was in fact used in the course of medical treatment to induce plaintiffs' consent to the procedure. While the question of proximate cause is a close one at this stage, the Supreme Court of Illinois has stressed that "the required allegation of proximate cause is minimal since that determination is best left to the trier of fact." Connick v. Suzuki Moto Co., Ltd., 174 Ill.2d 482, 504 (1996). The plaintiffs have therefore adequately plead a cause of action under the Illinois' Consumer Fraud Act.

3. Failure to Warn (Count VIII)

Plaintiffs assert that defendants failed to inform them that they were being administered "an unsafe, unreasonably dangerous drug compounded by NECC," and that the consent form she was provided "failed to inform [her] of the risks and benefits of the procedure[] before it was performed." Master Compl. ¶ 301-302. Defendants contend that "the Complaints do not contain any allegations that the Clinic Related Defendants knew or should have known that using preservative-free MPA or a compounded drug is unsafe or more dangerous than using a drug produced by an

FDA-regulated manufacturer." Docket # 1109, pg. 21. This is simply false. See Master Compl. ¶ 48-55, 151-206.

In Illinois, "consumers should principally look to their prescribing physician to convey the appropriate warnings regarding drugs, and it is the prescribing physician's duty to convey these warnings to the patients." Frye v. Medicare-Glaser Corp., 153 Ill. 2d 26, 34-35 (1992); see also Walton, 692 F. Supp.2d at 1019 ("physicians have a duty to warn patients of those dangers"). When taken in the light most favorable to the non-moving party, the factual allegations are sufficient to show dangerous propensities and unequal knowledge of those propensities. Plaintiffs have adequately plead a claim for failure to warn under Illinois law.

4. Illinois Product Liability Law (Count IX)

A claim for strict product liability in Illinois is comprised of three elements: (1) the product was defective, in that it was unreasonably dangerous in light of its nature and intended use; (2) the product's defective condition was present when it left the manufacturer's control; and (3) the defective condition of the product proximately caused plaintiff's injuries. Samansky v. Rush-Presbyterian-St. Luke's Med. Ctr., 208 Ill. App. 3d 377, 389 (1990). Defendants assert that they cannot be subject to strict liability because they were providers of a service.[8] The Illinois Supreme Court has held that "the dispensation of drugs and other medications by hospitals or other entities, where injury or disease result[s] from the existence of deleterious contaminants therein

[8] Defendants also argue that because the Master Complaint fails to specifically cite the Illinois Products Liability Law, it fails to adequately state a claim. This argument is utterly without merit.

would ... result in the application of the strict liability theory." Cunningham v. MacNeal Mem'l Hosp., 47 Ill. 2d 443, 453 (1970); Brandt v. Boston Scientific Corp., 204 Ill. 2d 640, 650 (2003) (ruling subsequent legislative abrogation applies to Cunningham "only as to human blood products and tissue.")

"Courts in strict liability cases must find that the defendant sold a product rather than services before imposing liability." Brandt, 204 Ill. 2d 640, 650. However, since the adoption of the Uniform Commercial Code ("UCC"), when a transaction in Illinois involves both the provision of goods and services, courts apply the "predominant purpose test" to determine whether there has been a transaction in goods. Pursuant to the predominant purpose test, "there is a 'transaction in goods' only if the contract is predominantly for goods and incidentally for services." In Re Yasmin & Yaz, 692 F. Supp. 2d at 1022. There is no question here that plaintiffs were billed, separately, for both a service (the act of injection), and a product (the MPA). However, the provision of the MPA was part-and-parcel with the service of its injection -- the only purpose of the visit was the injection itself, something only a physician with special skill could provide. Under Illinois law, there is no action for strict liability on the complaint as alleged.

5. Punitive Damages (Count XIV)

In Illinois, punitive damages may be awarded "when torts are committed with fraud, actual malice, . . . or when the defendant acts willfully, or with such gross negligence as to indicate a wanton disregard of the rights of others." Rockford Redi-Mix, Inc. v. Teamsters Local 325, 195 Ill. App. 3d 294, 309 (1990). The master complaint includes various assertions that defendants' actions "went beyond mere

thoughtlessness, inadvertence or error of judgment," Master Compl. at ¶ 237, and "constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect for the safety of patients," id. at ¶ 239. Plaintiffs also allege that defendants willfully and knowingly failed to abide by consumer safety regulations and withheld important safety information from patients. Id. at ¶ 249-50. Such allegations are enough to sustain plaintiffs' punitive damages claims at this early stage.

IV. Conclusion

It is ORDERED that the direct-filed actions be consolidated into their corresponding Illinois-filed actions.

Plaintiffs' claims for agency (Count X), civil conspiracy (Count XI), and battery (Count VII) are DISMISSED WITHOUT PREJUDICE per stipulation of the parties (Docket # 1603).

Defendants' motion to dismiss (Docket # 1208) is ALLOWED as to plaintiffs' claim for strict product liability (Count IX) and DENIED as to all other claims.

January 13, 2015
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE